November 01, 2017

HORIBA ABX SAS
Caroline Ferrer
Regulatory Affairs Manager
Parc Euromedecine
Rue du Caducee BP 7290
34184 Montpellier Cedex 4 – France

Re: K170353
Trade/Device Name: ABX MICROS ES 60 OT and ABX MICROS ES 60 CT
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: GKZ
Dated: September 28, 2017
Received: October 2, 2017

Dear Caroline Ferrer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR

803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Leonthena R. Carrington -S

Lea Carrington
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k170353

Device Name
ABX MICROS ES 60 OT (Open Tube model)
ABX MICROS ES 60 CT (Close Tube model)

Indications for Use *(Describe)*
The ABX MICROS ES 60 (OT and CT models) is a quantitative multi-parameter, automated hematology analyzer for in vitro diagnostic use in clinical laboratories to identify and enumerate the following parameters: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV, LYM%, LYM#, MON%, MON#, GRA%, GRA#, in K2EDTA and K3EDTA anticoagulated venous whole blood samples of adult patients and pediatric patients ≥ 1 month of age.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Premarket Notification [510(k)] Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is : k170353

1.0 Submitted by :

Company: HORIBA ABX SAS
HORIBA MEDICAL
Parc Euromédecine
Rue du Caducée – BP 7290
34184 Montpellier cedex 4
FRANCE

Contact Person: Caroline FERRER
Telephone (France): +33 467 141843
Email: caroline.ferrer@horiba.com

2.0 Date Submitted :

28th September 2017

3.0 Device Name and Classification :

Trade/Proprietary Name: **ABX MICROS ES 60**

Classification:

Device:	Counter, differential cell
Panel:	81 Hematology
Regulation number:	864.5220
Product Code:	GKZ
Class:	2

4.0 System description :

4.1 Device Description

The **ABX MICROS ES 60** is an automated hematology analyzer developed by HORIBA Medical and cleared under k141161.
No modification (hardware or software) to the **ABX MICROS ES 60** cleared device (k141161) was made to support the pediatric claim addition.

Performance verification has been done to support the pediatric claim addition.

The corresponding User Instructions for Use was updated to include this additional claim to the intended use.

4.2 Principles of Operation

The **ABX MICROS ES 60** performs hematology analyses using the following methods:

- RBC / PLT: Impedance
- WBC: Impedance
- HGB: Spectrophotometry
- DIFF: Impedance

The Principles of Operation are unchanged.

4.3 Modes of Operation

Two models of **ABX MICROS ES 60** are available.

- The Closed Tube (CT) instrument: it has a cap-piercing mechanism. The blood collection tube is placed directly in the analyzer without removing the cap.
- The Open Tube (OT) instrument: the cap form the blood collection tube must be removed before analyzing the sample.

4.4 Specimen Identification

Specimen identification is by manual sample identification with the use of a hand held barcode scanner.

4.5 Calibration

Calibration is a procedure that is performed during specific situations such as installation, maintenance or service intervention. It is performed by a HORIBA ABX SAS representative. It ensures that the precision and accuracy of the analyzer are acceptable, so that accurate measurements are performed by the analyzer.

There is no specific calibrator for pediatric addition.

4.6 Quality Control

Quality control allows the user to monitor a set of analyses based on known sample values and ranges over a period of several months. Statistical computation performed on these populations allows the extraction of qualitative information related to the stability of the instrument.
The manufacturer's instructions are to be followed for material and frequency of quality control analysis.

There is no specific control for pediatric addition.

4.7 Software

FDA has reviewed HORIBA ABX SAS's Hazard Analysis and Software Development processes for this line of product types during the 510(k) file k141161 review.

No change was made to the Hazard Analysis and Software Development processes relative to the pediatric use addition.

5.0 Intended use

5.1 Indications for Use :

The **ABX MICROS ES 60** (OT and CT models) is a quantitative multi-parameter, automated hematology analyzer for in vitro diagnostic use in clinical laboratories to identify and enumerate the following parameters: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV, LYM%, LYM#, MON%, MON#, GRA%, GRA#, in K2EDTA and K3EDTA anticoagulated venous whole blood samples of adult patients and pediatric patients ≥ 1 month of age.

5.2 Special Conditions for Use Statements:

For prescription use only

6.0 Comparison with the original device :

Similarities

Item	ABX MICROS ES 60 Device with additional pediatric intended use	ABX MICROS ES 60 (K141161) Previous Device
Manufacturer	HORIBA ABX SAS	HORIBA ABX SAS
Type of product	Automated blood cell counter	Automated blood cell counter
Parameters	**Complete Blood Cell Count (CBC)** WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV **Leukocyte Differential (DIFF):** LYM (# and %), MON (# and %), GRA (# and %)	**Complete Blood Cell Count (CBC)** Same **Leukocyte Differential (DIFF):** Same
Sample types	K2 and K3EDTA anti-coagulated whole blood	Same
Principles of measurements	RBC / PLT: Impedance WBC / DIFF: Impedance HGB: Spectrophotometry RDW, MCV, MCH, MCHC: Calculation	Same
Reagents	ABX Minidil LMG ABX Minilyse LMG or ABX Alphalyse 360 ABX Miniclean ABX Minipack LMG ABX Minoclair	Same
Calibrators	ABX Minocal	Same
Controls	ABX Minotrol 16 (3 levels)	Same
Throughput	OT / CT models: 60 / 50 samples per hour	Same
Dimensions (Height x Width x Depth)	43 cm x 36 cm x 36 cm	Same

Differences

Item	ABX MICROS ES 60 Device with additional pediatric intended use	ABX MICROS ES 60 (K141161) Previous Device
Intended Use	The **ABX MICROS ES 60** (OT and CT models) is a quantitative multi-parameter, automated hematology analyzer for in vitro diagnostic use in clinical laboratories to identify and enumerate the following parameters: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV, LYM%, LYM#, MON%, MON#, GRA%, GRA#, in K2EDTA and K3EDTA anticoagulated venous whole blood samples of adult patients and pediatric patients ≥ 1 month of age.	Same except: - sample type was venous only - intended population was adult patients only.

7.0 Substantial Equivalence Information :

The following tables show the similarities and differences between the candidate device and its predicate device identified below.

7.1 Predicate Device Name and 510(k) number:

For the validation of the pediatric use on the **ABX MICROS ES 60** the following predicate device was used during the clinical evaluation:

Candidate device	Predicate device	Manufacturer	Predicate 510(k) number
ABX MICROS ES 60	Sysmex XN Series, XN-10	SYSMEX	K112605

7.2 Comparison with predicate Device : Similarities

Item	**ABX MICROS ES 60 (k141161) Candidate device**	**Sysmex XN Series, XN-10 (k112605) Predicate Device**
Manufacturer	HORIBA ABX SAS	Sysmex
Type of product	Automated blood cell counter	Automated blood cell counter
Parameters	**Complete Blood Cell Count (CBC)** WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV **Leukocyte Differential (DIFF):** LYM (% and #)	**Complete Blood Cell Count (CBC)** WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, PLT, MPV **Leukocyte Differential (DIFF):** LYM (# and %),
Sample types	K2 and K3EDTA anti-coagulated venous samples	K2 and K3EDTA anti-coagulated whole blood
Principles of measurements	RBC / PLT: Impedance HGB: Spectrophotometry	RBC: Impedance (Sheath Flow) HGB: Spectrophotometry

7.3 Comparison with predicate Device : Differences

Item	**ABX MICROS ES 60 (k141161) Candidate device**	**Sysmex XN Series, XN-10 (k112605) Predicate Device**
Intended Use	The **ABX MICROS ES 60** (OT and CT models) is a quantitative multi-parameter, automated hematology analyzer for in vitro diagnostic use in clinical laboratories to identify and enumerate the following parameters: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV, LYM%, LYM#, MON%, MON#, GRA%, GRA#, in K2EDTA and K3EDTA anticoagulated venous whole blood samples of adult patients and pediatric patients ≥ 1 month of age.	The Sysmex® XN-10 and XN-20 modules are quantitative multi-parameter automated hematology analyzers intended for in vitro diagnostic use in screening patient populations found in clinical laboratories. The XN-Series modules classify and enumerate the following parameters: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, PLT, NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, NRBC%/#, IG%/#, , MPV, RET%/#, IRF, IPF, RET-He
Parameters	**Leukocyte Differential (DIFF):** MON (% and #) GRA (% and #) RDW-SD, NRBC%/#, IG%/#, , MPV, RET%/#, IRF, IPF, RET-He: parameters not available	**Leukocyte Differential (DIFF):** NEUT%/# MONO%/#, EO%/#, BASO%/# RDW-SD, NRBC%/#, IG%/#, , MPV, RET%/#, IRF, IPF, RET-He
Minimum Sample Volume **Specimen sample volume**	50 µL 10 µL	Sampler Mode – 88 µL Manual (Closed Cap) Mode – 88 µL Manual (Open Cap) Mode – 88 µL Dilution Mode – 70 µL
Dimensions	OT / CT models: 43 x 36 x 36 cm	85.5 cm x 64.5 cm x 75.5 cm
Weight	OT model: 14 kg CT model: 17 kg	57 kg
Throughput	OT / CT models: 60 / 50 samples per hour	100 samples/hour maximum depending on mode used.
Modes of Operation	Open Tube Mode Closed Tube Mode	Sampler Analysis Mode Manual Closed Analysis Mode Pre-dilute Analysis Mode Dilute sample 1:7
Principles of Measurement		
WBC, WBC Differential	Impedance	WBC: Radio-frequency (RF) / Direct-current (DC) Detection Method, Flow

Item	ABX MICROS ES 60 (k141161) Candidate device	Sysmex XN Series, XN-10 (k112605) Predicate Device
(LYM, MON, GRA)		Cytometry Methods using a Semiconductor Laser Particle characterization and identification is based on detection of forward scatter, fluorescence and adaptive cluster analysis. The XN-Series analyzers automatically classify cells from whole blood
Calibrator	ABX Minocal	XN CAL (XN-10/XN-20 Calibrator) XN CAL PF (Platelet F Calibrator)
Quality Controls	ABX Minotrol 16 (3 levels)	XN-Check - 3 Levels
Reagents	ABX Minidil LMG (Diluent) ABX Minilyse LMG or ABX Alphalyse 360 (Lyse) ABX Miniclean (Cleaner) ABX Minoclair (Concentrated cleaning reagent) ABX Minipack LMG (Reagent Pack)	CELLPACKTM DCL (Diluent) CELLPACKTM DFL (Diluent) LYSERCELL WNR (Lyse) LYSERCELL WDF (Lyse) LYSERCELL WPC (Lyse) FLUOROCELL WNR (Stain) FLUOROCELL WDF (Stain) FLUOROCELL RET (Stain) FLUOROCELL PLT (Stain) FLUOROCELL WPC (Stain)

8.0 Special Control/Guidance Document Referenced :

8.1 Standards Followed

- **CLSI EP09-A3:** Measurement Procedure Comparison and Bias Estimation Using Patient Samples – 2013
- **CLSI EP28-A3:** Defining, Establishing and Verifying Reference Intervals in the Clinical Laboratory – 2008

8.2 FDA Guidances Followed

- Guidance for Industry and FDA Staff : Format for Traditional and Abbreviated 510(k)s - 2005
- Final Guidance for Industry and FDA: Class II Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells – 2001

9.0 Summary of Performance Data :

9.1 Comparability with Predicate Device

A total of 137 venous whole blood specimens (collected in K2EDTA) from pediatric patients between 1 month and 21 years of age were collected and analyzed at two test sites in the US and one test site in France. Different instruments and operators were used at each site.
Each of the samples was analyzed in duplicate on the ABX MICROS ES 60 and once on the predicate XN Series, XN-10 from SYSMEX.
Bias was estimated at various data points, particularly around medical decision points, for each parameter. Bias was estimated for one replicate. Acceptance criteria were met for all measurands at all levels, except for RDW, due to the difference of calculation methods on the two analyzers. These findings support the claim that the ABX MICROS ES 60 candidate device and the XN Series, XN-10 predicate device are substantially equivalent, and demonstrate acceptable levels of bias for pediatric samples.

9.2 Reference Interval

69 (37 female and 32 male) normal pediatric samples (whole blood samples collected in K2EDTA) were analyzed, when possible in duplicate, on the ABX MICROS ES 60 at one test site in the US.
Results were compared to a pediatric reference range obtained from several US hospitals published ranges. Results were contained in the pediatric reference range, confirming the transference of the pediatric reference range below for the ABX MICROS ES 60:

Combined Pediatric Reference Range parameters		**MALE**			**FEMALE**		
		1 m - 2 y	**>2y - 12 y**	**>12 y - 21 y**	**1 m - 2 y**	**>2y - 12 y**	**>12 y - 21 y**
WBC	(10^3/mm^3)	5.0 – 20.0	3.4 – 17.0	3.5 - 13.0	5.0 – 20.0	3.4 – 17.0	3.5 - 13.0
RBC	(10^6/mm^3)	2.7 - 6.0	3.9 - 5.5	4.0 - 5.7	2.7 - 6.0	3.8 - 5.5	3.7 - 5.2
HGB	g/dL	8.9 - 18.0	10.2 – 15.5	11.0 - 18.0	9.0 - 18.0	10.2 – 15.5	10.6 – 16.0
HCT	%	28.0 - 55.0	31.0 - 45.0	33.9 - 49.0	27.7 - 55.0	31.0 - 45.0	32.9 – 49.0
MCV	µm^3	70 - 123	70 - 95	77 - 102	70 – 123	70 - 95	76.9 - 102
RDW	%	11.0 – 16.5	11.0 - 16.0	11.0 - 15.6	11.0 - 16.5	11.0 - 16.0	11.0 - 15.5
MCH	pg	22.7 - 36.0	23.0 - 33.0	25.0 - 35.0	24.4 – 35	23.7 - 33.0	24.8 - 35.0
MCHC	%	28 - 37	30 - 37	31 - 37	28 - 36	30 - 37	31 - 37
PLT	(10^3/mm^3)	140 - 562	140 - 450	140 - 450	140 – 597	140 - 450	140 - 450
MPV	µm^3	6.5 - 12.4	6.5 - 12.4	6.5 - 12.4	6.5 - 12.4	6.5 - 12.4	6.5 - 12.4
LYM#	(10^3/mm^3)	1.50 – 16.50	0.97 – 10.50	0.85 – 6.50	1.50 – 16.50	1.16 – 10.50	0.90 – 6.50
LYM%	%	26 - 86	15 - 75	12 - 53	27 - 87	17 - 75	13 - 50
MON#	(10^3/mm^3)	0.00 - 1.40	0.00 – 1.00	0.00 - 0.90	0.00 - 1.40	0.00 – 1.00	0.00 - 0.90
MON%	%	0 - 14	0 - 12	0 - 13	0 – 13	0 - 12	0 - 13
GRA#	(10^3/mm^3)	0.84 - 10.1	1.50 - 9.45	1.50 - 8.80	1.01 - 10.45	1.50 - 9.45	1.50 - 8.80
GRA%	%	10 - 80	12 - 85	31 - 87	9 - 86	12 - 81	31 - 87

These intervals are given in the labeling of the ABX MICROS ES 60.
However, expected values will vary with sample population and/or geographical location. HORIBA highly recommends that each laboratory establishes its own normal ranges based upon its local population.

10.0 Proposed Labeling :

The labeling is written as per the recommendations given in standard EN18113-2. It takes into account the requirements of 21 CFR Part 809.10.

11.0 Conclusion :

As per 21CFR Part §807.92(b)(3), the nonclinical and clinical tests demonstrate that the ABX MICROS ES 60 device is as safe, as effective, and performs as well as or better than the predicate device for pediatric population (≥1 month of age).

The submitted information in this premarket notification is complete and supports a substantial equivalence decision on pediatric use addition.